

A marked-up “Related Applications” section as well as a marked-up claim set are attached hereto.

An examination on the merits is respectfully requested.

Respectfully submitted,
O. GLOBERMAN et al.

Paul Fenster
Paul Fenster
Reg. No. 33,877

July 23, 2001
William H. Dippert, Esq.
Cowan, Liebowitz and Latman, P.C.
1133 Avenue of the Americas
New York, NY 10036-6799

Tel: (212) 790-9200

E

Marked-Up Version of Amendments

--RELATED APPLICATIONS

This application is a U.S. national filing of PCT Application No. PCT/IL00/00058, filed January 27, 2000. This application is a continuation in part of PCT application PCT/IB98/00523, which designates the U.S., the disclosure of which is incorporated herein by reference. This application is also related to two PCT applications, PCT/IL00/00055 and PCT/IL00/00056, which designate both designating the US, and both are filed on January 27, 2000 even date with the present application in the Israel receiving office, by applicant Disc-O-Tech Medical technologies Ltd. and have attorney dockets 110/01357 and 110/01362, the disclosures of which are incorporated herein by reference. This application is also related to PCT Application No. PCT/IB98/00523, the disclosure of which is incorporated herein by reference.--

110/02239 A01

MARKED-UP CLAIM SET

1. An expandable spacer, comprising:

an axial tube having a surface, a proximal end, a distal end and a length,

wherein, said surface defines a plurality of slits, said plurality of slits defining at least two axially displaced extensions, such that when said tube is axially compressed, said extensions extend out of said surface and define a geometry of an expanded spacer.

2. A spacer according to claim 1, wherein said at least two axially displaced extensions comprises at least three extensions, which three extensions extend in at least three different directions from said tube.

3. A spacer according to claim 1, wherein said at least two axially displaced extensions comprises at least four extensions, which four extensions extend in at least four different directions from said tube.

4. (Amended) A spacer according to ~~claimany of claims~~ 1-3, wherein said slits are straight.

5. (Amended) A spacer according to ~~claimany of claims~~ 1, 3, wherein said slits are curved.

6. (Amended) A spacer according to ~~claimany of claims~~ 1, 5, wherein said slits are defined by a cut in said tube.

7. (Amended) A spacer according to ~~claimany of claims~~ 1, 5, wherein said slits are defined by a section removed from said tube.

8. (Amended) A spacer according to ~~claimany of claims~~ 1, 7, wherein said slits are substantially parallel to said tube axis.

9. (Amended) A spacer according to ~~claimany of claims~~ 1, 7, wherein said slits are not parallel to said tube axis.

10. (Amended) A spacer according to ~~claimany of claims~~ 1, 9, wherein said slits are arranged in pairs of same length.

11. (Amended) A spacer according to ~~claimany of claims 1, -9,~~ wherein said slits are arranged in pairs of different lengths.

5 12. (Amended) A spacer according to ~~claimany of claims 1, -11,~~ wherein slits associated with one extension axially overlap slits associated with a second, axially displaced, extension.

13. (Amended) A spacer according to ~~claimany of claims 1, -12,~~ wherein said proximal end of said tube defines a proximal end-cap, which end-cap extends outside of a volume defined by
10 the geometry of said extended extensions.

14. (Amended) A spacer according to ~~claimany of claims 1, -13,~~ wherein said distal end of said tube defines a distal end-cap, which end-cap extends outside of a volume defined by the geometry of said extended extensions.

15 15. (Amended) A spacer according to claim 13, wherein at least one of said extensions is flush with said proximal end of said tube.

16. (Amended) A spacer according to claim 13, wherein at least one of said extensions is flush
20 with said distal end of said tube.

17. (Amended) A spacer according to ~~claimany of claims 1, -16,~~ comprising at least one spur axially extending from said spacer, to engage tissue adjacent said spacer.

25 18. Amended) A spacer according to claim 17, wherein said at least one spur comprises at least two spurs axially extending from said spacer.

19. (Amended) A spacer according to ~~claimany of claims 1, -18,~~ comprising an inner bolt.

30 20. (Amended) A spacer according to claim 19, wherein said inner bolt has a smooth exterior.

21. (Amended) A spacer according to claim 19, wherein said inner bolt has a threaded exterior.

F00240-240600

22. (Amended) A spacer according to ~~claimany of claims 19, 21,~~ wherein said bolt has a base, which base has an external diameter greater than an inner diameter of said tube, such that said base restricts axial motion of tube in one direction relative to the bolt.

23. (Amended) A spacer according to ~~claimany of claims 19, 22,~~ wherein said bolt has a head, which head locks against at least one end of said tube, to prevent axial expansion of said tube.

24. (Amended) A spacer according to claim 23, wherein said head is adapted to engage at least one protrusions extending from said tube toward said bolt head.

25. (Amended) A spacer according to claim 23, wherein said head comprises at least one protrusions extending from said head toward said tube, to engage said tube.

26. (Amended) A spacer according to claim 23, wherein said head comprises a flange, flared to have an outer diameter greater than an inner diameter of said tube.

27. (Amended) A spacer according to ~~claimany of claims 19, 26,~~ wherein said bolt is adapted to engage a pole element for holding said bolt during deployment of said spacer.

28. (Amended) A spacer according to claim 27, wherein said bolt has an inner thread for engaging said pole element.

29. (Amended) A spacer according to claim 27, wherein said bolt mechanically engages said pole element as long as a head of said bolt is constrained by said tube.

30. (Amended) A spacer according to ~~claimany of claims 1, 29,~~ wherein said spacer comprises a plurality of segments, each segment defining one or more extensions that extend from said spacer.

31. (Amended) A spacer according to claim 30, wherein said segments comprises at least two segment types, each segment type defining extensions that extend in different directions relative to said tube.

32. (Amended) A spacer according to claim 31, wherein said two segment types comprises a horizontal segment defining two extensions that extend along a line and a segment defining four extensions that extend at about $\pm 45^\circ$ to said two extensions.

5 33. (Amended) A spacer according to ~~claimany of claims 1, 32,~~ wherein an extension direction of at least one of said at least two extensions is normal to said tube.

34. (Amended) A spacer according to ~~claimany of claims 1, 32,~~ wherein an extension direction of at least one of said at least two extensions defines a sharp angle with said tube axis, in a
10 plane containing said tube axis.

35. (Amended) A spacer according to ~~claimany of claims 1, 32 or 34,~~ wherein at least one of said at least two extensions does not extend along a direction perpendicular to said tube.

15 36. (Amended) A spacer according to ~~claimany of claims 1, 35,~~ wherein at least one of said at least two extensions has, in a plane containing said tube axis, a profile of a triangle, with the tip pointed away from said tube.

37. (Amended) A spacer according to ~~claimany of claims 1, 35,~~ wherein at least one of said at
20 least two extensions has, in a plane containing said tube axis, a curved profile.

38. (Amended) A spacer according to ~~claimany of claims 1, 35,~~ wherein at least one of said at least two extensions has, in a plane containing said tube axis, a profile that narrows and then widens, along a direction away from the tube.
25

39. (Amended) A spacer according to ~~claimany of claims 1, 38,~~ wherein at least one of said at least two extensions has, in a plane perpendicular to said tube axis, a profile that narrows, along a direction away from the tube.

30 40. (Amended) A spacer according to ~~claimany of claims 1, 38,~~ wherein at least one of said at least two extensions has, in a plane perpendicular to said tube axis, a profile that narrows and then widens, along a direction away from the tube.

41. (Amended) A spacer according to ~~claimany of claims 1, -38,~~ wherein at least one of said at least two extensions has, in a plane perpendicular to said tube axis, a uniform profile.

42. (Amended) A spacer according to ~~claimany of claims 1, -41,~~ wherein at least one of said at least two extensions has, a pointed top profile.

43. (Amended) A spacer according to ~~claimany of claims 1, -41,~~ wherein at least one of said at least two extensions has, a top profile substantially the same size as a base of said extension.

44. (Amended) A spacer according to ~~claimany of claims 1, -41,~~ wherein at least one of said at least two extensions has, a top profile substantially the larger that a base of said extension.

45. (Amended) A spacer according to ~~claimany of claims 1, -44,~~ wherein said extensions are unevenly distributed along said axis.

46. (Amended) A spacer according to ~~claimany of claims 1, -44,~~ wherein said extensions are evenly distributed along said axis.

47. (Amended) A spacer according to ~~claimany of claims 1, -46,~~ wherein said extensions are unevenly distributed along a circumference of said tube.

48. (Amended) A spacer according to ~~claimany of claims 1, -46,~~ wherein said extensions are evenly distributed along a circumference of said tube.

49. (Amended) A spacer according to ~~claimany of claims 1, -48,~~ wherein said different ones of said extensions have different geometries.

50. (Amended) A spacer according to ~~claimany of claims 1, -49,~~ wherein said extensions are distributed in a spiral pattern.

51. (Amended) A spacer according to ~~claimany of claims 1, -50,~~ wherein said tube axis is coaxial with an axis of said expanded geometry.

52. (Amended) A spacer according to ~~claimany of claims 1, -49,~~ wherein said tube axis is parallel to an axis of said expanded geometry.

53. (Amended) A spacer according to ~~claimany of claims 1, -49,~~ wherein said tube axis is not-parallel to an axis of said expanded geometry.

54. (Amended) A spacer according to claim 53, wherein said tube axis and said expanded geometry axis are designed for oblique insertion of a spacer to be aligned, in its expanded state with vertebra.

55. (Amended) A spacer according to ~~claimany of claims 1, -54,~~ wherein said spacer has an expanded geometry cross-section of a circle.

56. (Amended) A spacer according to ~~claimany of claims 1, -54,~~ wherein said spacer has an expanded geometry cross-section of a rectangle.

57. (Amended) A spacer according to ~~claimany of claims 1, -56,~~ wherein a cross-section of said expanded geometry varies along an axis of said expanded geometry.

58. (Amended) A spacer according to ~~claimany of claims 1, -56,~~ wherein a cross-section diameter of said expanded geometry varies along an axis of said expanded geometry.

59. (Amended) A spacer according to claim 58, wherein said cross-section is rectangular and wherein said cross-sectional diameter increases along said expanded geometry axis.

60. (Amended) A spacer according to ~~claimany of claims 1, -59,~~ wherein a cross-section diameter of said tube varies along an axis of said tube.

61. (Amended) A spacer according to ~~claimany of claims 1, -60,~~ wherein a cross-section of said tube varies along an axis of said tube.

62. (Amended) A spacer according to ~~claimany of claims 1, -59,~~ wherein said tube has a circular cross-section.

63. (Amended) A spacer according to ~~claimany of claims 1, -59~~, wherein said tube has an elliptical cross-section.

64. (Amended) A spacer according to ~~claimany of claims 1, -59~~, wherein said tube has a rectangular cross-section.

65. (Amended) A spacer according to ~~claimany of claims 1, -64~~, wherein said tube axis is bent, when the spacer is unexpanded.

66. (Amended) A spacer according to ~~claimany of claims 1, -61~~, wherein said tube axis is straight when the spacer is unexpanded.

67. (Amended) A spacer according to ~~claimany of claims 1, -66~~, wherein said tube axis is bent when the spacer is expanded.

68. (Amended) A spacer according to ~~claimany of claims 1, -66~~, wherein said tube axis is straight when the spacer is expanded.

69. (Amended) A spacer according to ~~claimany of claims 1, -68~~, comprising a ratchet mechanism to maintain said spacer in an expanded configuration.

70. (Amended) A spacer according to ~~claimany of claims 1, -69~~, comprising at least one portion of said spacer that prevents axial contraction of said spacer.

71. A spacer according to claim 70, wherein said at least one portion comprises a pair of tabs that abut when the spacer is axially contracted.

72. A spacer according to claim 70, wherein said at least one portion comprises a strip that folds and forms a thickness between two opposing sides of said spacer, preventing the opposing sides from meeting.

73. (Amended) A spacer according to ~~claimany of claims 1, -72~~, comprising at least protrusion on at least one of said extensions, to prevent collapsing of said extension.

TESETE

74. (Amended) A spacer according to ~~claimany of claims 1, 72,~~ comprising at least protrusion on at least on of said extensions, to interlock said two extensions.

75. (Amended) A spacer according to ~~claimany of claims 1, 74,~~ comprising at least one interconnecting element for interconnecting said extensions when the extensions are expanded.

76. A spacer according to claim 75, wherein said interconnecting element comprises a flexible wire.

77. A spacer according to claim 75, wherein said interconnecting element comprises a substantially rigid strut.

78. (Amended) A spacer according to ~~claimany of claims 1, 77,~~ wherein at least one of said extensions comprises only bending joints.

79. (Amended) A spacer according to ~~claimany of claims 1, 77,~~ wherein at least one of said extensions comprises at least one twisting joint.

80. (Amended) A spacer according to ~~claimany of claims 1, 77,~~ wherein at least one of said extensions comprises a lift-up-extension in which a significant axial section of the tube is lifted away from said tube to form said expanded geometry.

81. (Amended) A spacer according to ~~claimany of claims 1, 80,~~ wherein at least one of said extensions comprises at least two legs that are coupled by a extension top.

82. (Amended) A spacer according to ~~claimany of claims 1, 80,~~ wherein at least one of said extensions comprises at least three legs that are coupled by a extension top.

83. (Amended) A spacer according to ~~claimany of claims 1, 80,~~ wherein at least one of said extensions comprises at least four legs that are coupled by a extension top.

84. (Amended) A spacer according to ~~claimany of claims 1, 83,~~ wherein at least one of said extensions comprises at least two legs, which legs are aligned with the tube axis.

85. (Amended) A spacer according to ~~claimany of claims 1, -84~~, wherein a plurality of annealed locations are provided on said spacer to assist in expansion of said spacer.

86. (Amended) A spacer according to ~~claimany of claims 1, -85~~, wherein a plurality of etched locations are provided on said spacer to assist in expansion of said spacer.

87. (Amended) A spacer according to ~~claimany of claims 1, -86~~, wherein a plurality of holes are provided on said spacer to assist in expansion of said spacer.

88. A spacer according to claim 87, wherein said holes distribute stress in said spacer.

89. (Amended) A spacer according to ~~claimany of claims 1, -84~~, wherein said spacer is annealed as a unit.

90. (Amended) A spacer according to ~~claimany of claims 1, -89~~, wherein said spacer comprises means for changing the axial length of the spacer over time, after the spacer is implanted.

91. (Amended) A spacer according to ~~claimany of claims 1, -90~~, wherein said spacer is formed of metal.

92. (Amended) A spacer according to ~~claimany of claims 1, -90~~, wherein said spacer is formed of plastic.

93. (Amended) A spacer according to ~~claimany of claims 1, -90~~, wherein said spacer is formed of a combination of distinct zones of different materials.

94. (Amended) A spacer according to ~~claimany of claims 1, -93~~, wherein said spacer comprises an elastic material, which is elastically deformed by the extension deformation.

95. (Amended) A spacer according to ~~claimany of claims 1, -94~~, wherein said spacer comprises a plastic material, which is plastically deformed by the extension deformation.

96. (Amended) A spacer according to ~~claimany of claims 1, -95~~, wherein said spacer comprises a super-elastic material, which is super-elastically deformed by the extension deformation.

97. (Amended) A spacer according to ~~claimany of claims 1, -96,~~ wherein said spacer comprises a shape-memory material.

98. (Amended) A spacer according to ~~claimany of claims 1, -97,~~ wherein said spacer is adapted to be axially deformed under axial pressures of over 20 Kg.

99. (Amended) A spacer according to ~~claimany of claims 1, -97,~~ wherein said spacer is adapted to be axially deformed under axial pressures of over 30 Kg.

100. (Amended) A spacer according to ~~claimany of claims 1, -97,~~ wherein said spacer is adapted to be axially deformed under axial pressures of over 50 Kg.

101. (Amended) A spacer according to ~~claimany of claims 1, -97,~~ wherein said spacer is adapted to be axially deformed under axial pressures of over 70 Kg.

102. (Amended) A spacer according to ~~claimany of claims 1, -97,~~ wherein said spacer is adapted to be axially deformed under axial pressures of over 90 Kg.

103. (Amended) A spacer according to ~~claimany of claims 1, -102,~~ wherein said spacer is adapted to remain expanded in a vertebra of an active human, when placed with the tube axis perpendicular o a spine of said human.

104. (Amended) A spacer according to ~~claimany of claims 1, -103,~~ wherein said tube has a cross-sectional diameter smaller than 2 times the maximal cross-sectional diameter of said expanded geometry.

105. (Amended) A spacer according to ~~claimany of claims 1, -103,~~ wherein said tube has a cross-sectional diameter smaller than 4 times the maximal cross-sectional diameter of said expanded geometry.

106. (Amended) A spacer according to ~~claimany of claims 1, -105,~~ wherein said expanded geometry is sized to fit between two human vertebrae.

107. (Amended) A spacer according to ~~claimany of claims 1, 106,~~ wherein said extensions have tips and wherein said tips has a surface fill factor of at least 20% relative to the contact surface of a target vertebra with the spacer geometry.

5 | 108. (Amended) A spacer according to ~~claimany of claims 1, 106,~~ wherein said extensions have tips and wherein said tips has a surface fill factor of at least 40% relative to the contact surface of a target vertebra with the spacer geometry.

10 | 109. (Amended) A spacer according to ~~claimany of claims 1, 106,~~ wherein said extensions have tips that contact a surface of target vertebra and wherein said tips has a surface fill factor of at least 60% relative to the contact surface of the target vertebra with the spacer geometry.

15 | 110. (Amended) A spacer according to ~~claimany of claims 1, 109,~~ wherein said expanded geometry covers at least 40% of the surface of a target vertebra, previously contacting a disc.

111. (Amended) A spacer according to ~~claimany of claims 1, 109,~~ wherein said expanded geometry covers at least 60% of the surface of a target vertebra, previously contacting a disc.

20 | 112. (Amended) A spacer according to ~~claimany of claims 1, 109,~~ wherein said expanded geometry covers at least 80% of the surface of a target vertebra, previously contacting a disc.

113. A spacer, comprising:

25 | an elongate body having a surface and having a maximum cross-section at a portion thereof; and

a plurality of at least two axially displaced extensions radially extending from said body,

30 | wherein, said extensions are axially dense on at least 40% of said body, including said portion, such that at least 50% of a surface area of said body is covered by extensions, wherein said dense extensions define a cross-section having a diameter at least two times a diameter of said body cross-section and wherein said extensions are formed of said surface.

114. A spacer according to claim 113, wherein said extensions are dense on at least 50% of said body.

115. A spacer according to claim 113, wherein said extensions are dense on at least 70% of said body.

116. (Amended) A spacer according to ~~claimany of claims 1, 115~~, wherein said spacer is coated with a bio-active coating.

117. A spacer according to claim 116, wherein said bio-active coating retards bone ingrowth.

118. A spacer according to claim 116, wherein said bio-active coating promotes bone ingrowth.

119. (Amended) A spacer according to ~~claimany of claims 1, 118~~, wherein said extensions comprises spikes.

120. (Amended) A spacer according to ~~claimany of claims 1, 119~~, wherein an extensions designed to carry greater stress has an increased strength over another extension.

121. (Amended) A spacer according to ~~claimany of claims 1, 120~~, wherein said spacer has an angular orientation.

122. (Amended) A spacer according to ~~claimany of claims 1, 121~~, wherein at least two of said at least two extensions are designated to hold apart two vertebra.

123. (Amended) A spacer according to ~~claimany of claims 1, 122~~, wherein said spacer is lordotic.

124. (Amended) A spacer according to ~~claimany of claims 1, 123~~, wherein at least one of said extensions is adapted to embed in vertebral bone.